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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/808,832	03/15/2001	Robert A. Copeland	PH-7134	5618

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[REDACTED] ART UNIT [REDACTED] PAPER NUMBER

1654

DATE MAILED: 09/04/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Advisory Action</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/808,832	COPELAND ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Jeffrey E. Russel	1654	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

THE REPLY FILED 15 August 2003 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

**PERIOD FOR REPLY** [check either a) or b)]

- a)  The period for reply expires 4 months from the mailing date of the final rejection.
- b)  The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.  
ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1.  A Notice of Appeal was filed on \_\_\_\_\_. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2.  The proposed amendment(s) will not be entered because:
  - (a)  they raise new issues that would require further consideration and/or search (see NOTE below);
  - (b)  they raise the issue of new matter (see Note below);
  - (c)  they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
  - (d)  they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: See attachment.

3.  Applicant's reply has overcome the following rejection(s): None.
4.  Newly proposed or amended claim(s) \_\_\_\_\_ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
5.  The a) affidavit, b) exhibit, or c) request for reconsideration has been considered but does NOT place the application in condition for allowance because: See attachment.
6.  The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
7.  For purposes of Appeal, the proposed amendment(s) a) will not be entered or b) will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: None.

Claim(s) objected to: 15-29, 31 and 32.

Claim(s) rejected: 1-14, 30 and 35-39.

Claim(s) withdrawn from consideration: \_\_\_\_\_.

8.  The proposed drawing correction filed on \_\_\_\_\_ is a) approved or b) disapproved by the Examiner.
9.  Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_.
10.  Other: \_\_\_\_\_

1. The Sequence Listing filed August 15, 2003 is not approved. Numerous amino acid sequences recited in the specification and claims and subject to the sequence disclosure rules are not found in the proposed new sequence listing. For example, the elected sequence which was designated as SEQ ID NO:186 in the Sequence Listing filed June 28, 2001 does not correspond to SEQ ID NO:52 or to any other sequence of the proposed new sequence listing. The elected sequence comprises 7 amino acids, and SEQ ID NO:52 of the proposed new sequence listing has only 4 amino acid residues.

Also, the sequence listing filed August 15, 2003 was not accompanied by a statement of no new matter, as required by 37 CFR 1.825(a).

2. The substitute specification filed August 15, 2003 is not approved and will not be entered. Firstly, Applicants did not submit a clean copy of the substitute specification as required by 37 CFR 1.125. Note that 37 CFR 1.121(b)(3)(ii) refers to 37 CFR 1.125 for the requirements of submitting a substitute specification. Secondly, the substitute specification as proposed by Applicants would result in the presence of numerous amino acid sequences which are subject to the sequence disclosure rules but which are not recited in the proposed new sequence listing or identified by SEQ ID NOS as required by 37 CFR 1.821(d). See, e.g., page 22, lines 2-17, of the proposed substitute specification. Finally, the proposed substitute specification uses the language “provided as SEQ ID NO:” (see, e.g., page 21, lines 28-29) rather than just the standard sequence identification language “SEQ ID NO:”. It is not clear what this change of terminology is intended to import.

3. The proposed amendment filed August 15, 2003 incorrectly lists the status of claims 33 and 34. Claims 33 and 34 were previously canceled in the amendment filed April 3, 2003, and are not withdrawn from consideration.

4. The proposed amendments to the claims are in improper format under 37 CFR 1.121. As of July 30, 2003, the amendment format required by 37 CFR 1.121(c) has changed, and deletions from a claim must be shown using strike-throughs rather than brackets. See the Final Rule published at 68 Fed Reg 38611, also located at

<http://www.uspto.gov/web/offices/pac/dapp/opla/preognotice/moreinfoamdtprac.htm>. Even under the previous version of 37 CFR 1.121, the combination of bracketing and underlining which occurs in proposed amended claim 1, proviso (f), would have been improper.

5. Proposed new claims 40-42 raise new issues under 35 U.S.C. 112, second paragraph. The claim language “E<sup>CP</sup> is an enzyme cleavable peptide selected from: γ-E -P-L-G is R-γ-E -P-L-G-(O-benzyI-S)-Y-L-; provided as SEQ ID NO: 52:”, which occurs in each of the claims, is unclear. The quoted section of the claim does not seem to provide a listing of E<sup>cp</sup> groups from which to select; the statement that “γ-E -P-L-G is R-γ-E -P-L-G-(O-benzyI-S)-Y-L-“ is incorrect because these are two different peptides; and the meaning of the terminology “provided as SEQ ID NO: 52:” is not known.

6. The proposed amendments to the claims filed August 15, 2003, had they been entered, would have overcome the rejections under 35 U.S.C. 112, second paragraph, and the prior art rejections set forth in the final Office action mailed May 8, 2003.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey E. Russel at telephone number (703) 308-3975. The examiner can normally be reached on Monday-Thursday from 8:30 A.M. to 6:00 P.M. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor Brenda Brumback can be reached at (703) 306-3220. The fax number for Technology Center 1600 for formal communications is (703) 872-9306; for informal communications such as proposed amendments, the fax number (703) 746-5175 can be used. The telephone number for the Technology Center 1600 receptionist is (703) 308-0196.



Jeffrey E. Russel

Primary Patent Examiner

Art Unit 1654

JRussel

September 3, 2003